



## BEST PRACTICE PRINCIPLES

# INCONTINENCE-ASSOCIATED DERMATITIS: **MOVING PREVENTION FORWARD**

## Addressing evidence gaps for best practice

Identifying causes and risk factors for IAD

IAD and pressure ulceration

IAD assessment and severity-based categorisation

IAD prevention and management strategies

Proceedings from the Global IAD Expert Panel

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## FOREWORD

Incontinence-associated dermatitis (IAD) represents a significant health challenge worldwide and is a well-recognised risk factor for pressure ulcer development<sup>1</sup>. Recent consensus work has identified gaps in our current understanding and practice<sup>2</sup>. The ability of clinicians to deliver evidence-based practice is hampered by lack of standardised definitions and terminology, high-quality studies, and international or national guidelines.

In September 2014, a group of international experts met in London to review knowledge deficits in IAD and to advance best practice principles to address these gaps. Key topics included: risk assessment for IAD; the role of IAD in pressure ulcer development; assessment and categorisation of IAD; and development of a severity-based approach to treatment. This document reflects the important discussions and outcomes of this event. Following the meeting, an initial draft was developed and underwent extensive review by the expert working group. The document was then sent to a wider group of experts for further review.

For the clinician providing hands-on patient care, the information presented in this document details practical guidance on how to assess, prevent and manage IAD based on available evidence and expert opinion. For clinical leaders, a step-by-step guide for advancing IAD prevention within their care setting is provided in addition to information on developing a structured prevention programme.

It is the expert panel's intention that this document will help promote effective skin care strategies for the prevention of IAD, improving patient quality of life and clinical outcomes worldwide. It is also hoped that this document will raise awareness of the need for accurate, standardised data collection for IAD, and the development of high-quality studies to advance our evidence base.

Professor Dimitri Beckman, Chair

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# Targeting incontinence-associated dermatitis

## DEFINING IAD

Incontinence-associated dermatitis (IAD) describes the skin damage associated with exposure to urine or stool. It causes considerable discomfort and can be difficult, time-consuming and expensive to treat<sup>2</sup>.



IAD is a type of irritant contact dermatitis (inflammation of the skin) found in patients with faecal and/or urinary incontinence<sup>3</sup>

IAD is also known as perineal dermatitis, diaper rash and many other names (Box 1) and is included within a broader group of skin conditions that are referred to as moisture-associated skin damage (MASD). The term IAD is preferred as it distinguishes skin problems arising directly from contact with urine and/or faeces due to incontinence from other conditions and acknowledges that the condition may affect more than the perineal area and people of any age.

This document has a glossary that defines key terms used within the document (see Appendix A, page 20)

### BOX 1 | Terms that have been used for IAD

- |                                  |                       |
|----------------------------------|-----------------------|
| ■ Diaper/napkin/nappy dermatitis | ■ Moisture lesions    |
| ■ Diaper/napkin/nappy rash       | ■ Perineal dermatitis |
| ■ Irritant dermatitis            | ■ Perineal rash       |

The current version of the World Health Organization's International Classification of Diseases (ICD-10, in use since 1994) contains coding for diaper dermatitis but does not contain separate coding for IAD<sup>4</sup>. The expert panel recommend that the term IAD is defined and included in the ICD and that this should be differentiated from diaper dermatitis, age being an important distinction. The use of consistent terminology for IAD will facilitate research and improve education of healthcare providers.

## HOW MANY PATIENTS ARE AFFECTED BY IAD?

Where data are collected, IAD is a significant problem. However, in many countries, the precise number of patients affected by IAD is not known. This is at least partly because of the difficulties of recognising the condition and distinguishing it from Category/Stage I and II pressure ulcers<sup>1</sup> (see p.8). The lack of an internationally validated and accepted method for IAD data collection further contributes to a wide variation in prevalence and incidence figures.

Existing data suggest IAD is a common problem in healthcare settings. Studies have estimated that it has:

- **prevalence** (i.e. proportion of patients with IAD at a defined point in time) of 5.6%-50%<sup>5-9</sup>
- **incidence** (i.e. proportion of patients who develop IAD over time) of 3.4%-25%<sup>18,10,11</sup>.

The wide variations in reported prevalence and incidence of IAD are likely to have a number of causes including differences in care setting and prevalence of incontinence, and the lack of widely accepted clinical criteria for the diagnosis of IAD. Epidemiological studies of IAD must report prevalence and incidence rates in relation to the proportion of the population that is incontinent<sup>9</sup>.



The terms 'prevalence' and 'incidence' are well defined but may be applied incorrectly. These terms should not be used interchangeably to avoid confusion in any study results obtained<sup>12</sup>

# Recognising IAD



**Figure 1 |** Patches of denudement present over buttocks with surrounding erythema and maceration. Pressure ulcer over coccyx (photo courtesy of Prof Dimitri Beeckman)



**Figure 2 |** Diffuse erythema involving perianal area, buttocks, sacrococcygeal area and thighs. Indistinct margins with desquamation at periphery of affected area. Patchy areas of superficial erosion on left buttock (photo courtesy of Heidi Helvia)

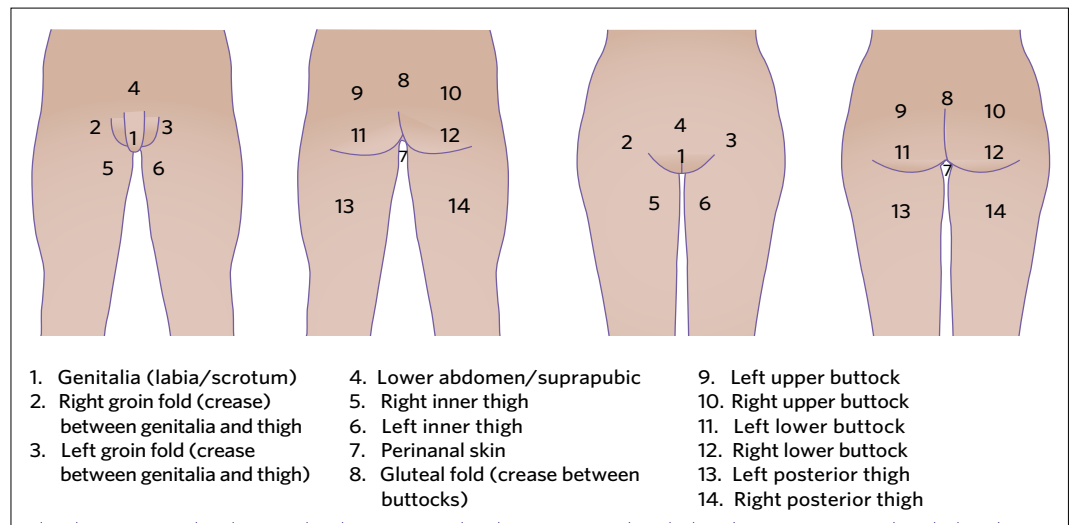
In individuals with light skin, IAD appears initially as erythema which can range from pink to red. In patients with darker skin tones, skin may be paler, darker, purple, dark red or yellow<sup>13</sup>. The affected area usually has poorly defined edges and may be patchy or continuous over large areas.

Because of the underlying inflammation, areas of IAD where skin is intact may feel warmer and firmer than surrounding unaffected skin. Lesions including vesicles or bullae, papules or pustules may be observed. The epidermis may be damaged to varying depths; in some cases the entire epidermis may be eroded exposing moist, weeping dermis (Figure 1).

Patients with IAD can experience discomfort, pain, burning, itching or tingling in the affected areas. Pain may be present even when the epidermis is intact. In addition, the development of IAD can result in an undue burden of care, loss of independence, disruption in activities and/or sleep, and reduced quality of life, worsening with frequency and quantity of soiling<sup>14,15</sup>.

Patients with IAD are susceptible to secondary skin infections, candidiasis being one of the most common secondary infections associated with IAD (Figure 2). A single study found that 32% of patients with IAD had a rash indicative of a fungal infection<sup>9</sup>. It typically appears as a bright red rash spreading from a central area. Satellite lesions (i.e. pinpoint papules or pustules) appear at the margins of the rash extending into normal skin<sup>16</sup>. In darker skin tones or with long standing infection, the central area of candidiasis may be darkened<sup>8</sup>. Fungal rashes may also present as a non-specific confluent papules, which may be difficult to diagnose clinically and microbiological cultures should be taken to guide treatment<sup>9</sup>.

The distribution of affected skin in IAD is variable and may extend well beyond the perineum (the area between the anus and the vulva or scrotum) depending on the extent of skin contact with urine and/or faeces<sup>3</sup>. In urinary incontinence, IAD tends to affect the folds of the labia majora in women or the scrotum in men, and groin folds. It can also extend over the lower abdomen and the anterior and medial thighs. IAD associated with faecal incontinence originates in the perianal area<sup>17</sup>. It often involves the gluteal fold and buttocks and can extend upward over the sacrococcygeal area and back and downward over the posterior thighs (Figure 3).



**Figure 3 |** Areas of skin that may be affected by IAD (adapted from<sup>18</sup>)



Depending on the extent of contact with urine and/or faeces, IAD may affect large areas of skin, not just the skin of the perineum

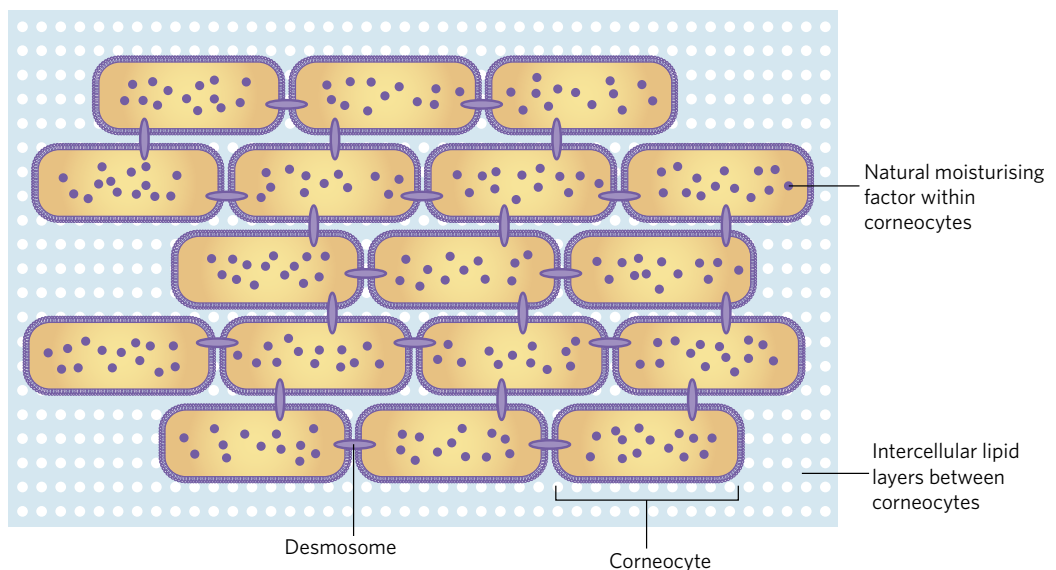
# How does incontinence cause IAD?

The main barrier of the skin is located in the outermost layer, the stratum corneum. Depending on the skin area, it comprises up to 15–20 layers of flattened skin cells called corneocytes<sup>19</sup>. These are formed from keratinocytes in the epidermis. The stratum corneum is constantly renewed; as the upper layer of corneocytes in the stratum corneum is shed, a new lower layer of corneocytes develops to maintain the integrity of the skin barrier.

The corneocyte layers are embedded in lipids in a pattern that has been likened to that of bricks and mortar in a wall (Figure 4). The corneocytes are also joined to each other by protein links known as desmosomes. These add stability to the stratum corneum matrix structure<sup>19</sup>. The whole structure is important in regulating water movement into and out of the stratum corneum, ensuring sufficient hydration for effective skin function, but preventing overhydration<sup>20</sup>.

Corneocytes contain a variety of proteins, sugars and other substances that together are known as natural moisturising factor (NMF). The NMF helps to hydrate the whole structure to maintain an effective and flexible barrier<sup>21,22</sup>.

**Figure 4 |** Model of stratum corneum structure in which the corneocytes are the bricks and the mortar is composed of intercellular lipid layers (adapted from<sup>22</sup>)



The healthy skin surface is acidic with a pH of 4–6. pH plays a fundamental role in the skin's barrier (acid mantle) and assists in regulating the resident bacteria on the skin (skin microbiome). However, an acidic pH has an additional role in ensuring the optimal stratum corneum cohesion and barrier function<sup>23</sup>.



**IAD represents disruption to the normal barrier function of the skin, which triggers inflammation. Key mechanisms involved are overhydration of the skin and an increase in pH<sup>3,13,24</sup>**

## IAD AND SKIN BARRIER FUNCTION

With incontinence, water from urine and/or faeces is pulled into and held in the corneocytes. This overhydration causes swelling and disruption of the structure of the stratum corneum, and leads to visible changes in the skin (e.g. maceration)<sup>25</sup>. As a result of excessive hydration, irritants may more easily penetrate the stratum corneum to exacerbate inflammation. When skin is overhydrated, the epidermis is also more prone to injury from friction caused by contact with clothing, incontinence pads or bed linen<sup>8</sup>.

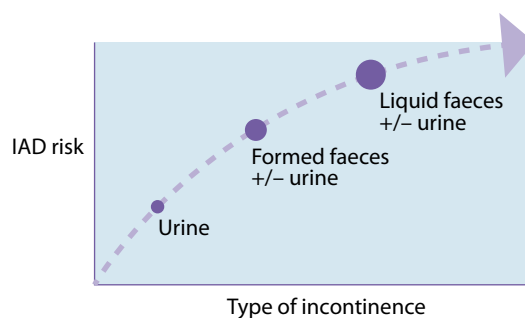
With exposure to urine and/or faeces, skin becomes more alkaline. This occurs because skin bacteria convert the substance urea (a product of protein metabolism found in urine) to ammonia which is alkaline. The increase in skin pH is likely to allow micro-organisms to thrive and increase the risk of skin infection.

Faeces contain lipolytic (lipid-digesting) and proteolytic (protein-digesting) enzymes capable of damaging the stratum corneum. Clinical experience has demonstrated that liquid faeces are more damaging than formed faeces as liquid faeces tend to be highest in digestive enzymes<sup>17,26</sup>. Enzymes can also act on urea to produce ammonia, further increasing the pH seen in urinary incontinence. Enzymes are more active at a higher pH, so the risk of skin damage is increased with alkaline changes. This may explain why the combination of urine and faeces observed in mixed incontinence is more irritating to the skin than either urine or stool alone<sup>21</sup>.



**Patients with faecal incontinence +/- urinary incontinence are at higher risk of developing IAD than those with urinary incontinence alone<sup>9</sup> (Figure 5)**

**Figure 5 |** Faeces act as a direct chemical irritant to the skin and loose stools increase the risk and severity of IAD



There is emerging interest in the possibility that certain medications (e.g. steroids or chemotherapeutic agents or their metabolites) that are excreted in urine or faeces may have a role in the development of IAD. In one study, antibiotic usage was found to be a statistically significant risk factor for IAD<sup>27</sup>.

Poor or inappropriate management of incontinence may also contribute to the development of IAD. For example:

- prolonged exposure to urine and faeces due to infrequent change of incontinence products or limited cleansing
- absorptive or incontinence containment devices may exacerbate overhydration by holding moisture against the skin surface<sup>13</sup>, especially if they have a plastic backing
- thick occlusive skin protectant products may limit fluid uptake of absorbent incontinence products<sup>28</sup> causing overhydration of the stratum corneum
- frequent skin cleansing with water and soap is detrimental to skin barrier function by damaging the corneocytes, removing lipids, increasing dryness and creating friction<sup>24</sup>
- aggressive cleansing technique (e.g. using regular washcloths) can increase frictional forces and abrade the skin<sup>29</sup>.

# Does IAD contribute to pressure ulcer development?

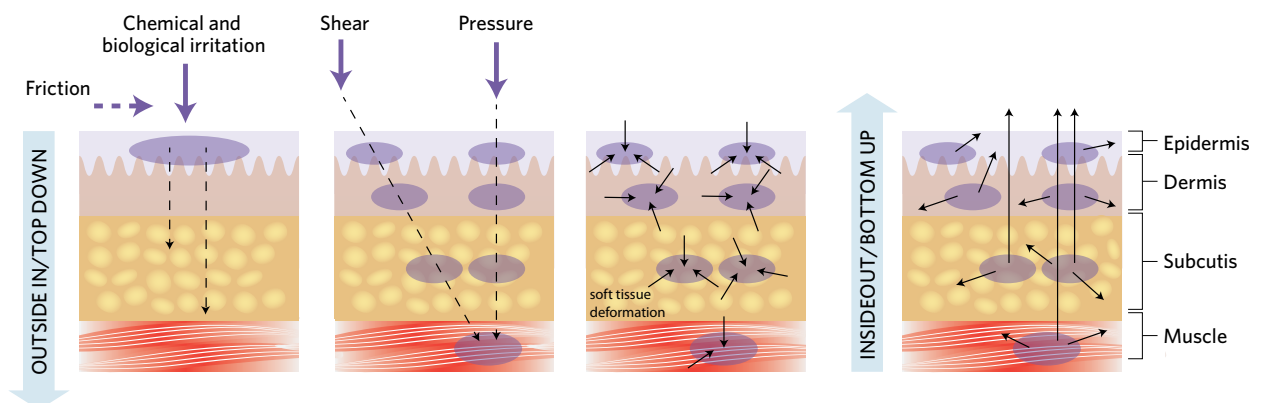
Incontinence is a well-recognised risk factor for the development of pressure ulcers<sup>1,30</sup>. Until recently, the relationship between IAD and pressure ulcers had not been explored.

IAD and pressure ulcers have a number of risk factors in common and both conditions are most likely to occur in patients who have poor health and problems with mobility<sup>13,31</sup>. Once IAD occurs, there is a high risk for pressure ulcer development as well as an increased risk of infection and morbidity<sup>32</sup>. The risk of developing pressure ulcers has also been found to increase as the severity score for IAD increases<sup>33</sup>.



**Patients vulnerable to skin injury from pressure and shear are also likely to be vulnerable to skin damage resulting from moisture, friction and irritants<sup>34</sup>**

IAD and pressure ulcers have different aetiologies but may co-exist: IAD is a 'top down' injury, i.e. damage is initiated on the surface of the skin, while pressure ulcers are believed to be 'bottom up' injuries, where damage is initiated by changes within soft tissues below and within the skin<sup>35,36</sup> (Figure 6).



**Figure 6 | Possible mechanisms of action in IAD and pressure ulcer development**

The concept that not all superficial skin injuries are caused by pressure and may be due to other aetiologies<sup>37</sup> was used to create a framework for delineating superficial skin changes from deep pressure ulcers<sup>38</sup>. Superficial skin changes are predominantly caused by frictional forces on the skin surface<sup>39</sup>. The literature further identifies changes in skin microclimate conditions (due to trapped perspiration or urine and/or faeces at the skin-surface interface), which may increase the risk for superficial pressure ulceration<sup>40</sup>.

It is well accepted that wet skin demonstrates a higher coefficient of friction (CoF), and that this effect is exacerbated by the constituents of urine<sup>41</sup>. Using computational modelling, it has been demonstrated that the increase in skin-support CoF simultaneously reduces tissue tolerance to pressure and shear stresses within deeper tissues<sup>42</sup>. This increases soft tissue deformation that ultimately causes a pressure ulcer to form<sup>43</sup>. In addition to mechanical forces, inflammation may play a role in making skin more susceptible to pressure injury. The challenge for practitioners is that these lesions can occur in the same location or in very close proximity, making classification problematic.



**Incontinence is a risk factor for pressure ulcers, but IAD can occur in the absence of any other pressure ulcer-associated risk factors and vice versa**

Although additional research is needed to clarify the nature of this relationship, it follows that prevention of IAD using steps to reduce frictional forces is likely to contribute to the prevention of superficial pressure ulcers and should be considered an essential component of any pressure ulcer prevention programme.

# Identifying patients at risk of IAD

Although risk assessment tools for IAD have been developed<sup>44,45</sup> these are not widely used in clinical practice, while pressure ulcer risk assessment tools such as the Braden Scale, Norton and Waterlow scale were not designed for IAD, nor do they adequately predict risk of IAD development.



**The expert panel do not recommend the development of a separate risk assessment tool for IAD, although awareness of key risk factors for IAD is needed**

**Key risk factors for IAD include<sup>5,7,17,46,47</sup>:**

- Type of incontinence:
  - Faecal incontinence (diarrhoea/formed stool)
  - Double incontinence (faecal and urinary)
  - Urinary incontinence
- Frequent episodes of incontinence (especially faecal)
- Use of occlusive containment products
- Poor skin condition (e.g due to aging/steroid use/diabetes).
- Compromised mobility
- Diminished cognitive awareness
- Inability to perform personal hygiene
- Pain
- Raised body temperature (pyrexia)
- Medications (antibiotics, immunosuppressants)
- Poor nutritional status
- Critical illness.

Although increased age is associated with higher prevalence of incontinence, age does not appear to be an independent risk factor for IAD<sup>47</sup>.



**The presence of any urinary and/or faecal incontinence, even in the absence of other risk factors, should trigger implementation of an appropriate IAD prevention protocol to minimise/prevent exposure to urine and stool and protect skin**



# IAD assessment and categorisation

All patients with urinary and/or faecal incontinence should have their skin assessed regularly to check for signs of IAD. This should be at least once daily but may be more frequent based on number of episodes of incontinence. Special attention should be paid to skin folds or areas where soilage or moisture may be trapped. Incontinent patients at very high risk of IAD, e.g. individuals with diarrhoea or with multiple risk factors, should have skin assessments performed more frequently (Box 2).



Assessment for IAD should be incorporated into a general skin assessment and performed as part of a pressure ulcer prevention/continence care programme



Figure 7 | Patient with evidence of erythema in gluteal cleft (photo courtesy of Prof Dimitri Beeckman)



Assessment and documentation of continence status should also include deviations from normal bladder and/or bowel function and any follow-up actions

A few tools have been developed for assessment of IAD (Box 3). While some of these have been investigated for validity, their use in day-to-day practice remains limited. This is due in part to the lack of evidence that these tools improve clinical decision making and care; further studies are needed to detect any potential benefits.

## BOX 3 | IAD assessment tools


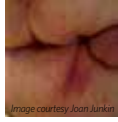


- IAD Assessment and Intervention Tool (IADIT)<sup>48</sup>
- Incontinence-associated dermatitis and its severity (IADS)<sup>18</sup>
- Skin Assessment Tool<sup>16,49</sup>

## ADOPTING A SIMPLE CATEGORISATION TOOL

The expert panel recognises the need for a systematic assessment of IAD. It recommends the adoption of a simplified approach to categorising IAD based on the level and severity of skin injury (Table 1).

The categories do not necessarily relate to the natural history of IAD and are not intended to suggest how IAD may develop and progress. This categorisation tool may prove useful in directing care when clearly linked to a care protocol (see Figure 8 and Table 5) and for monitoring and research purposes.

**TABLE 1 | IAD Severity Categorisation Tool**

Clinical presentation	Severity of IAD	Signs**
 <small>Image © 3M, 2014</small>	No redness and skin intact (at risk)	Skin is normal as compared to rest of body (no signs of IAD)
 <small>Image courtesy Joost Linker</small>	Category 1 - Red* but skin intact (mild)	Erythema +/-oedema
 <small>Image © 3M, 2014</small> moderate	Category 2 - Red* with skin breakdown (moderate-severe)	As above for Category 1 +/-vesicles/bullae/skin erosion +/- denudation of skin +/- skin infection
 <small>Image courtesy Joost Linker</small> severe		
* Or paler, darker, purple, dark red or yellow in patients with darker skin tones		
**If the patient is not incontinent, the condition is not IAD		

### DIFFERENTIATING IAD FROM PRESSURE ULCERS AND OTHER SKIN CONDITIONS

It is often difficult for clinicians to correctly identify IAD and to distinguish it from pressure ulcers (Category/Stage I or II)<sup>34</sup> and other skin conditions, such as contact dermatitis (e.g. from textiles or skin products), or lesions due to infections (e.g. herpes simplex) or perspiration (e.g. intertrigo).



#### If the patient is not incontinent, the condition is not IAD

In healthcare systems where pressure ulcers are used as a quality of care indicator and management of a pressure ulcer is not reimbursable, misdiagnosis of IAD as a pressure ulcer has potentially serious implications<sup>8,13</sup>.

Correct assessment and diagnosis of IAD is important and necessary to ensure that:

- the patient receives appropriate treatment
- documentation is accurate
- quality reporting and correct reimbursement can be facilitated.

To further complicate assessment, IAD and pressure ulcers may co-exist and strict differentiation may not be possible until a management protocol has been in place for some time (e.g. 3-5 days) and response to treatment has been observed.

The difficulties of distinguishing IAD from Category/Stage I and II pressure ulcers have prompted an ongoing debate about whether only Category/Stage III (full-thickness skin loss) and Category/Stage IV (full-thickness tissue loss) pressure ulcers should be reported for quality of care and reimbursement purposes.

Table 2 summarises differences between IAD and pressure ulcers that may help to distinguish the conditions (see p.9).

**TABLE 2 | Distinguishing IAD from pressure ulcers (adapted from<sup>316</sup>)**

Parameter	IAD	Pressure ulcer
History	Urinary and/or faecal incontinence	Exposure to pressure/shear
Symptoms	Pain, burning, itching, tingling	Pain
Location	Affects perineum, perigenital area; buttocks; gluteal fold; medial and posterior aspects of upper thighs; lower back; may extend over bony prominence	Usually over a bony prominence or associated with location of a medical device
Shape/edges	Affected area is diffuse with poorly-defined edges/may be blotchy	Distinct edges or margins
Presentation/depth	Intact skin with erythema (blanchable or non-blanchable), with/without superficial, partial-thickness skin loss	Presentation varies from intact skin with non-blanchable erythema to full-thickness skin loss  Base of wound may contain non-viable tissue
Other	Secondary superficial skin infection (e.g. candidiasis) may be present	Secondary soft tissue infection may be present



**Assessment relies on clinical observation and visual inspection. No bedside (point-of-care) technologies are available to aid in the assessment and diagnosis of IAD**

Measurement of passive water loss through skin (known as transepidermal water loss (TEWL) is used to measure skin barrier function<sup>50</sup>. In general, an increase in TEWL (i.e. an increase of water diffusion through skin) is indicative of a disturbed skin barrier function. However, TEWL measurements are complicated to use outside of the research setting and interpretation is difficult. Although adaptations of this technique (and other skin parameters) could be developed to aid diagnosis, their advantages over standard clinical assessment are unclear at the present time.

An e-learning training tool (PUCLAS) has been developed. This tool has been used to help healthcare providers distinguish IAD from pressure ulcers (<http://www.puclas3.ucvgent.be>)<sup>51,52</sup>.



**If the aetiology of erythema is not clear a standard bundle of interventions for the management of both IAD and pressure ulcer prevention should be implemented and reviewed to assess anticipated response**

# Prevention and management of IAD

Two key interventions are critical for the prevention and management of IAD:

- **Manage incontinence** to identify and treat reversible causes (e.g. urinary tract infection, constipation, diuretics) to reduce, or ideally eliminate skin contact with urine and/or faeces.
- **Implement a structured skin care regimen** to protect the skin exposed to urine and/or faeces and help restore an effective skin barrier function.

These interventions will be similar for both prevention and management of IAD (Figure 8).



**Prevention of IAD should be aimed at all incontinent patients with the aim of promoting positive outcomes and avoidance of patient injury and harm**

## MANAGE INCONTINENCE

Management of incontinence requires a thorough assessment of the patient to identify the aetiology of incontinence and establish a comprehensive plan of care. Treatment of reversible causes usually begins with non-invasive behavioural interventions such as nutritional and fluid management or toileting techniques<sup>53</sup>.

In general, because they hold moisture against the skin, absorbent incontinence management products such as adult briefs should be reserved, where practical, for ambulant patients or when the patient is sitting out in a chair<sup>13</sup>. However, newer products with improved fluid handling properties may be considered as an adjunct to a structured skin care regimen to help avoid occlusion and overhydration of the stratum corneum<sup>54,55</sup>.

Patients with IAD in acute settings may require temporary diversion of urine and/or faeces away from the skin to allow adequate skin protection and/or healing<sup>3</sup>. For urinary incontinence, this may require use of an indwelling urinary catheter, although this should be seen as a last resort due to the high risk of nosocomial infection. Management of liquid faeces may be achieved with a faecal management system (FMS)<sup>56</sup>. If a FMS is unavailable, a faecal pouch (similar to that used for faecal ostomies) can be applied. Large gauge urinary catheters are not recommended for use as rectal tubes due to the risk of damage to the anal continence structure.



**There should be visible improvement in the skin condition and reduction in pain in 1-2 days following the implementation of an appropriate skin care regimen, with resolution within 1-2 weeks<sup>11</sup>. For patients who continue to have unresolved continence issues, seek advice from specialist continence advisors, where possible**

## IMPLEMENT A STRUCTURED SKIN CARE REGIMEN

A structured skin care regimen consists of two key interventions:

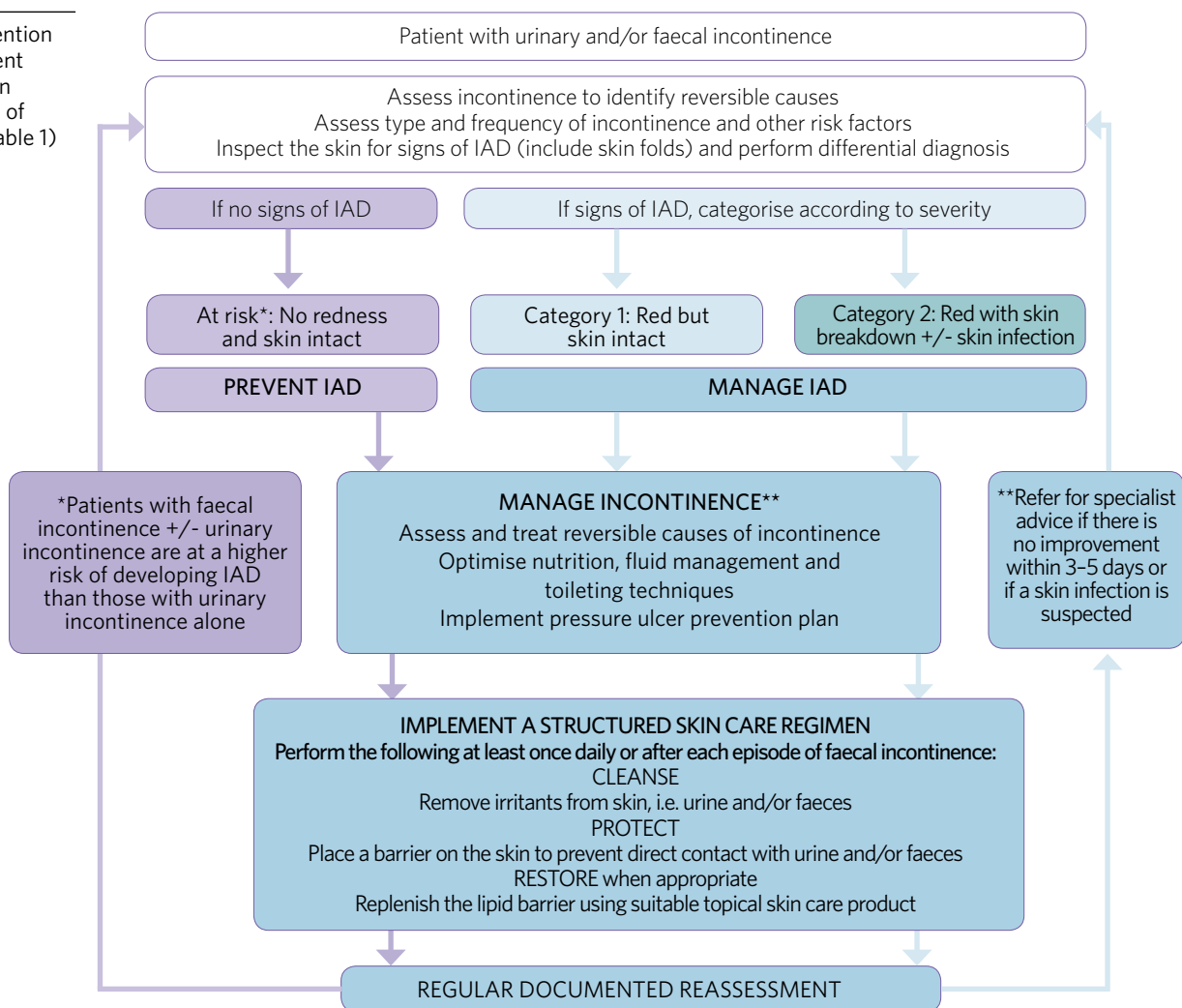
- **Cleansing** the skin (CLEANSE)  
To remove urine and/or faeces, i.e. the source of irritants that cause IAD. This should be done prior to the application of a skin protectant as part of a routine process to remove urine and faeces
- **Protecting** the skin (PROTECT)  
To avoid or minimise exposure to urine and/or faeces and friction.

Patients may benefit from an additional RESTORE step to support and maintain skin barrier function using a suitable leave-on skin care product (see p.15).



**Structured skin care regimens that incorporate gentle cleansing and the use of skin protectants have been shown to reduce the incidence of IAD<sup>24</sup>. This may also be associated with a reduction in the development of Category/Stage I pressure ulcers<sup>57</sup>**

**Figure 8 |** Prevention and management of IAD based on categorisation of severity (see Table 1)



### Product selection

Products used for the prevention and management of IAD are available in a wide variety of formulations. Ingredients vary considerably and the terminology used to describe the properties of products can be confusing<sup>2</sup>. Box 4 (p.12) lists the characteristics of the ideal product for use in the prevention and management of IAD agreed by the expert panel.

### Considerations when selecting products in the EU

Products that carry a CE mark fulfil the essential requirements of the EU Medical Device Directive 93/42/EEC, and are subject to clinical evaluation, vigilance and post-market surveillance procedures. These products are designed and manufactured by companies holding an ISO 13485 certificate. Manufacturers are subjected to regular audits by notified bodies as well as by national Ministries of Health e.g. MHRA or their locally designated control bodies. Increasingly, ISO 13485 is being required, or is at least beneficial, in supporting regulations around the world.

Since 11 July 2013 cosmetic products sold in the EU are subject to the EU Cosmetics Regulation No.1223/2009. This requires registration in a database and outlines safety requirements for cosmetic products. However, these are focused primarily on toxicology requirements of the product ingredients; it does not pose requirements for design, manufacture, quality control, usability or clinical efficacy. Cosmetic product manufacturers are also not subjected to audits by notified bodies or designated control bodies and they do not require ISO certification.

Outside of the EU products are approved by relevant government institutions and it is important to be aware of national or local registration procedures for effective product selection.

#### BOX 4 | General characteristics of the ideal product for prevention and management of IAD

- Clinically proven to prevent and/or treat IAD
- Close to skin pH (Note: pH is not relevant to all products, e.g. those that do not contain hydrogen ions, including some barrier films)
- Low irritant potential/hypoallergenic
- Does not sting on application
- Transparent or can be easily removed for skin inspection
- Removal/cleansing considers caregiver time and patient comfort
- Does not increase skin damage
- Does not interfere with the absorption or function of incontinence management products
- Compatible with other products used (e.g. adhesive dressings)
- Acceptable to patients, clinicians and caregivers
- Minimises number of products, resources and time required to complete skin care regimen
- Cost-effective

#### CLEANSE

Traditionally standard soap, water and a regular washcloth have been used to cleanse the skin after incontinence episodes to remove urine and faeces and other soilage. However, standard soap is alkaline and has been shown to change skin pH, attacking the corneocytes and potentially damaging skin barrier function. This may be further impaired by the nubby texture of regular washcloths which can cause friction damage<sup>29</sup>; in addition, the application of water alone can impair skin barrier function as evidenced by an increase in TEWL — considered to be a sensitive indicator of barrier health<sup>22</sup>. Furthermore, infection control issues associated with the use of wash basins have been identified<sup>58</sup>.



**A skin cleanser with a pH range similar to normal skin is preferred over traditional soap<sup>29</sup>. This should be labelled as being indicated or suitable for use in the management of incontinence**

Skin cleansers contain compounds (surfactants) that reduce surface tension and allow soilage and debris (such as oil and dead skin cells) to be removed with a minimum of force on the skin (Table 3). There are several categories of surfactants based on their chemical structure and cleansers often contain more than one surfactant. Non-ionic (i.e. non-charged) surfactants are preferred for skin cleansers because of their gentleness. Manufacturers should be willing to provide information on the type of surfactant in their formulation.

**TABLE 3 | Surfactant categories (adapted from<sup>59-60</sup>)**

Surfactant type	Examples
<b>Non-ionic:</b> <ul style="list-style-type: none"><li>■ uncharged</li><li>■ generally less irritating than anionic surfactants</li></ul>	<ul style="list-style-type: none"><li>■ Polyethylene glycol (PEG)</li><li>■ Acyl-polyglycoside (APG)</li><li>■ Polysorbates</li><li>■ Octoxynols</li></ul>
<b>Anionic:</b> <ul style="list-style-type: none"><li>■ negatively-charged</li><li>■ high pH</li></ul>	<ul style="list-style-type: none"><li>■ Sodium lauryl sulfate (SLS)</li><li>■ Sodium laureth sulfate</li><li>■ Sodium sulphosuccinate</li><li>■ Sodium stearate</li></ul>
<b>Amphoteric:</b> <ul style="list-style-type: none"><li>■ positively- and negatively-charged</li><li>■ generally less irritating than anionic surfactants</li></ul>	<ul style="list-style-type: none"><li>■ Cocamido propyl betaine</li></ul>

Skin cleansers for incontinence are often referred to as 'perineal' skin cleansers. They are formulated as liquid solutions or lotions. Liquid cleansers may be packaged in spray bottles or impregnated into a cloth. Cleansers may also be packaged as a container that converts the liquid into a foam; foams are preferred by some clinicians as they do not drip or run down skin. Cleansers may contain additional skin-conditioning ingredients used to provide skin protection and/or moisturisation. Most incontinence skin cleansers are designed to be used full strength and should not be diluted<sup>59</sup>.



**Although an understanding of the function of individual ingredients in skin cleansers may be useful, the performance characteristics of an individual skin cleansing product (e.g. how well it cleanses or likelihood of benefit to skin barrier function) is highly dependent on the combination of ingredients used**

The ideal frequency of skin cleansing in incontinence has not been determined. Cleansing itself may disrupt skin barrier function and so a balance has to be found between removing irritants due to incontinence and preventing or minimising irritation through cleansing. Many skin cleaners are 'no-rinse', can remain on the skin after application and are quick-drying, eliminating friction caused by manual drying.

In addition to providing a benefit for skin, use of no-rinse cleansers has been shown to save staff time and improve efficiency<sup>62-64</sup>. Continence care wipes are made of smooth material to reduce friction damage. These have been found to enhance adherence to protocols, reduce burden of care and improve staff satisfaction<sup>24</sup>.

Box 5 lists the principles of skin cleansing in the prevention and management of IAD.

**BOX 5 | Principles of CLEANSE in the prevention and management of IAD (adapted from<sup>16,65,66</sup>)**

- Cleanse daily and after every episode of faecal incontinence
- Use gentle technique with minimal friction, avoid rubbing/scrubbing of skin
- Avoid standard (alkaline) soaps
- Choose a gentle, no-rinse liquid skin cleanser or pre-moistened wipe (designed and indicated for incontinence care), with a pH similar to normal skin
- If possible, use a soft, disposable non-woven cloth
- Gently dry skin if needed after cleansing



**This expert panel recommends that the skin of patients who are incontinent should be cleansed at least once daily and after each episode of faecal incontinence**

Cleansing skin to remove irritants is critical. Where skin cleansers are not available, cleansing with a gentle soap and water is an option. If a gentle soap is not available, cleansing with plain water is preferred. However, the expert panel suggest that this is a minimum standard and where possible, the use of no-rinse cleansers suitable for the management of incontinence is recommended.

### **PROTECT**

After cleansing, skin should be protected to prevent IAD. Skin protectants are used in the prevention and treatment of IAD to form a barrier between the stratum corneum and any moisture or irritant. In addition to protecting the skin from urine and faeces, when IAD is present the application of a skin protectant should help promote resolution of IAD and allow the skin barrier to recover. Skin protectants are also called moisture barriers and provide variable protection from moisture and irritants depending on the skin protectant ingredients and overall formulation (Table 4, p14).

Skin protectants may be formulated as creams, pastes, lotions or films (<http://www.dermweb.com/therapy/common.htm>):

- **Creams** are emulsions (i.e. mixtures) of oils/lipid substances and water and can vary significantly. For a cream to function as a skin protectant, it must contain a known barrier ingredient (e.g. petrolatum, zinc oxide, dimethicone) alone or in combination. These ingredients may be called out as 'active' ingredients on the label if required by the regulatory authorities in a given country
- **Ointments** are semi-solid, commonly formulated with a petrolatum base and are more greasy than creams
- **Pastes** are a mixture of absorbent material (e.g. carboxymethylcellulose) and ointments; increases the consistency so they adhere to moist denuded skin but are more difficult to rub off
- **Lotions** are liquids that contain a suspension of inert or active ingredients
- **Films** are liquids that contain a polymer (e.g. acrylate based) dissolved in a solvent. Upon application, it forms a transparent protective coating on the skin. They are not labelled as having an active ingredient.

The performance of the principal ingredient will vary according to the overall formulation and usage (e.g. amount applied). All products should be used according to manufacturer's instructions

**TABLE 4 | Characteristics of the main types of skin protectant ingredients (adapted from<sup>3,13,17,28,67,68</sup>)**

Principal skin protectant ingredient	Description	Notes
Petrolatum (petroleum jelly)	Derived from petroleum processing Common base for ointments	<ul style="list-style-type: none"> <li>■ Forms an occlusive layer, increasing skin hydration</li> <li>■ May affect fluid uptake of absorbent incontinence products</li> <li>■ Transparent when applied thinly</li> </ul>
Zinc oxide	White powder mixed with a carrier to form an opaque cream, ointment or paste	<ul style="list-style-type: none"> <li>■ Can be difficult and uncomfortable to remove (e.g. thick, viscous pastes)</li> <li>■ Opaque, needs to be removed for skin inspection</li> </ul>
Dimethicone	Silicone-based; also known as siloxane	<ul style="list-style-type: none"> <li>■ Non-occlusive, does not affect absorbency of incontinent products when used sparingly</li> <li>■ Opaque or becomes transparent after application</li> </ul>
Acrylate terpolymer	Polymer forms a transparent film on the skin	<ul style="list-style-type: none"> <li>■ Does not require removal</li> <li>■ Transparent, allows skin inspection</li> </ul>



**The performance of an individual product is determined by the total formulation and not just the skin protecting ingredient(s)**

Box 6 lists the principles of skin protectant use in the prevention and management of IAD agreed by the expert panel.

**BOX 6 | Principles of skin protectant use in the prevention and management of IAD**

- Apply the skin protectant at a frequency consistent with its ability to protect the skin and in line with manufacturer's instructions
- Ensure the skin protectant is compatible with any other skin care products, e.g. skin cleansers that are in use
- Apply the skin protectant to all skin that comes into contact with or potentially will contact urine and/or faeces



## RESTORE

Patients may benefit from an additional step to support and maintain the integrity of the skin barrier. This is accomplished by using topical leave-on skin care products (often termed moisturisers). Skin care products are diverse and can contain a very wide range of ingredients with many different properties. Typically they contain lipophilic materials or oils (known as emollients) but can have other chemical compositions. Some skin care products are formulated with lipids similar to those found in healthy stratum corneum (e.g. ceramides) and are intended to reduce dryness and restore the lipid matrix<sup>69</sup>. Another category of ingredient are humectants, which are substances that function by drawing in and holding water in the stratum corneum; common examples include glycerine and urea.



**Clinicians and caregivers should check the ingredients of any product to be applied to the skin of a patient to ensure it does not contain any substance to which the patient is sensitive or allergic and is indicated for use in patients with incontinence**

Some previous IAD recommendations have advised a standard approach that included moisturisers for both prevention and treatment. However, it is important to recognise that many moisturisers contain a mixture of emollients and humectants, and not all are capable of skin barrier repair. In particular, a humectant is not indicated for use on skin that is overhydrated or where maceration is present as it will attract further moisture to the area.

## COMBINING PRODUCTS

A skin care regimen may involve the use of separate products for CLEANSE and PROTECT. When CLEANSE, PROTECT and RESTORE is desired for prevention, separate products may be used or a single product that combines these functions may be selected. Some skin protectants also include moisturising ingredients; moisturising ingredients may also be incorporated into liquid cleansers. Continence care wipes (i.e. 3-in-1 products) that are intended to CLEANSE, PROTECT and RESTORE may have the advantage of simplifying care by combining products to reduce the number of steps involved, saving clinician/caregiver time and potentially encouraging adherence to the regimen<sup>8,16,70</sup>.



**A skin care product or combination product that has skin protective/restorative actions is recommended to prevent IAD in at-risk patients**

## MANAGEMENT OF SKIN INFECTION AND IAD

In most cases, candidiasis is treated topically with the use of an antifungal cream or powder. These should be used in combination with a skin protectant (e.g. acrylate terpolymer barrier film)<sup>65</sup>.

Although commonly caused by *Candida albicans*, other candida species can be responsible for secondary infections in IAD. Microbiological samples should be collected prior to treatment with topical antifungal preparations. Seek medical opinion and differentiate between other possible dermatological conditions, especially if the patient is not responding to standard treatment.

Due to increasing antimicrobial resistance judicious use of these products is warranted; there is no evidence to support routine use of topical antimicrobial products in the prevention and management of IAD.

### IS THERE A ROLE FOR DRESSINGS IN IAD MANAGEMENT?

In some cases of severe IAD where skin loss is present (e.g. weeping erosions, denudement), dressings that promote moist wound healing can be used. Successful application, however, may be significantly challenged by skin contours such as folds and creases and the presence of frequent or continuous moisture and soiling. Dressings are best suited to flat or minimally contoured locations such as the buttocks or sacral area<sup>2</sup>.

### EVALUATE PATIENT RESPONSE FOR ONGOING CARE

It is important that patients are re-evaluated regularly. The results of the assessment and any modifications to the plan of care should be documented. The chosen plan should be adhered to in order to assess whether it is effective. If there is no improvement in the skin after 3–5 days of a structured skin care regimen or skin condition deteriorates, the care plan should be reevaluated and referral to a specialist may be indicated.

Table 5 provides an overview of the role of skin care products in the prevention and management of IAD.

**TABLE 5 | Interventions for prevention and management based on the severity of IAD**

Patient with urinary +/- faecal incontinence	ACTIONS			
No redness and skin intact (at risk)	MANAGE INCONTINENCE EDUCATE PATIENTS AND CAREGIVERS	<b>CLEANSE*, PROTECT** &amp; RESTORE***</b>		REFER FOR SPECIALIST ADVICE if there is no improvement within 3–5 days OR if a skin infection is suspected
		PREVENTION: select option 1 or 2		
1		Continece care wipe (3-in-1: cleanser + skin protectant + moisturiser) <b>ADD</b> skin protectant (e.g. dimethicone-containing product) if extra skin protection is required		
2		Skin cleanser OR bathing/cleansing wipe <b>PLUS</b> Skin protectant (e.g. acrylate terpolymer film or petrolatum-based product or dimethicone-containing product)		
MANAGEMENT: select option 1 or 2				
1		Continece care wipe (3-in-1: cleanser + skin protectant + moisturiser) <b>ADD</b> skin protectant (e.g. acrylate terpolymer barrier film) if worsening erythema/skin condition		
2		Skin cleanser OR bathing/cleansing wipe <b>PLUS</b> Skin protectant (e.g. acrylate terpolymer barrier film or dimethicone-containing product)		
1		Continece care wipe (3-in-1: cleanser + skin protectant + moisturiser) <b>ADD</b> skin protectant (e.g. acrylate terpolymer barrier film) if worsening erythema/skin condition		
2		Skin cleanser OR bathing/cleansing wipe <b>PLUS</b> Skin protectant (e.g. acrylate terpolymer barrier film, dimethicone-containing product or zinc oxide based ointment or paste)		
		<b>AND</b> consider containment devices (e.g. FMS/faecal pouch)		
Plus skin infection	As for Category 2 <b>PLUS</b> Take a microbiological sample when possible and use result to decide on appropriate therapy (e.g. antifungal cream, topical antibiotic, anti-inflammatory product)			
<p>*Cleansing should take place daily and after each episode of faecal incontinence</p> <p>**Skin protectants should be applied according to the manufacturer's instructions</p> <p>***For skin that is overhydrated or where maceration is present, do not use skin care products that trap moisture or are formulated to attract moisture</p>				

# Moving prevention forward

## BOX 7 | Areas identified for future research into IAD

- More detailed and wider ranging studies of prevalence and incidence using standardised definitions and study methodology
- Natural history of IAD: aetiology, pathophysiology and progression
- Impact of IAD on quality of life
- Validation of the IAD Severity Categorisation Tool (see p.8)
- Further investigation of TEWL and other skin parameters as potential parameters for diagnosing or predicting IAD
- Further investigation of link between incontinence, IAD and pressure ulcers
- Comparative effectiveness of different products and skin care regimens in prevention and management of IAD
- Investigation of the effect of therapeutic bed linen (eg silk-like textiles) in the prevention and management of IAD
- Health economics of IAD.

## REDUCING KNOWLEDGE GAPS

Several issues draw attention to the need for education on IAD. Inaccurate assessment, misclassification of IAD as pressure ulcers<sup>2</sup>, absent or inadequate protocols<sup>71</sup> and lack of product understanding and misuse are among key knowledge deficits and issues<sup>72</sup>.

Key content areas for education include:

- Cause, signs and symptoms of IAD
- Differentiation from other conditions, e.g. pressure ulcers, herpetic lesions
- Impact of IAD on patients
- Strategies for prevention and treatment of IAD.

## IDENTIFYING COSTS OF CARE

Estimating the cost of the prevention and management of IAD is complicated because the costs involved may be difficult to distinguish from the costs of managing incontinence and preventing and managing pressure ulcers. An indication that management of IAD is likely to be a significant cost to healthcare systems comes from an estimate that in 1995 in the USA skin conditions associated with incontinence cost US\$136.3 million<sup>2</sup>.

A major cost driver in the prevention and management of IAD within any care setting is likely to be the cost of clinician and caregiver time. Any financial analysis also has to take account for the cost of linen changes, laundry costs, as well as other factors such as aprons, gloves, skin cleansers and protectants and disposing of soiled items<sup>56</sup>.

Economic considerations in terms of nursing time and consumables were studied by Bale et al<sup>57</sup> following the introduction of a structured skin care protocol (skin cleanser, barrier cream and barrier film) in two nursing homes. The authors found that the presence of IAD was significantly lower three months after introduction. The presence of Category/Stage I pressure ulcers was also significantly reduced. The new regimen produced a reduction in time taken to deliver skin care, saving just over 34 minutes of staff time per patient per day<sup>57</sup>. The average saving per day per patient in staff costs was GBP £8.83 (US \$13.75) for qualified staff and GBP £3.43 (US \$5.33) for unqualified staff (based on 2004 costs)<sup>57</sup>.

Similarly, an audit found that it may take at least two nurses up to 20 minutes to clean a patient after an episode of faecal incontinence<sup>56</sup>. An effective IAD prevention or management regimen that simplifies skin care and reduces contact time is likely to be cost-effective<sup>2</sup>. The potential impact of IAD in long-term care settings is high because of the large numbers of patients cared for and the often high prevalence of incontinence.

Another study evaluated the economics of four different skin care regimens in over 900 nursing home residents. Three of the regimens included applying a skin protectant after each episode of incontinence, but the other (a polymer film barrier) only three times weekly. The study found no significant difference in IAD rates between the four regimens, but the total cost (including product, labour and other supplies) per incontinence episode was significantly lower with the barrier film than with the petroleum ointments or zinc oxide<sup>10</sup>. A further review of the evidence concluded that polymer products appear to be at least as clinically effective and potentially more cost-effective in preventing IAD than non-polymer products<sup>73</sup>.

**These studies provide limited economic data and further research is needed to quantify the clinical and economic benefits of different protocols of care in different clinical settings. Other areas for future research are listed in Box 7**



# Making the case for IAD prevention

The reality of funding for healthcare is that choices have to be made about how money and resources are allocated for maximum overall benefit<sup>74</sup>.

When convincing payors and insurers to fund preventative measures, e.g. the implementation of a structured skin care regimen for incontinent patients, the arguments should be grounded in data relevant to the care setting involved and focused on the perspective of the identified key stakeholders. The absence of a standard ICD10 classification for consistent data collection makes it difficult to quantify the impact of IAD on healthcare resources and outcomes. However, identifying a need for prevention may prompt data collection or analysis of existing records.

It is known that IAD contributes to pressure ulcer development<sup>1,31</sup>. Decreasing hospital-acquired IAD could potentially decrease hospital-acquired pressure ulcers and the costs associated with those. While economic data for pressure ulcer prevention cannot necessarily be extrapolated to IAD, it may be indicative of potential costs involved in IAD prevention. From pressure ulcer health economic data<sup>31,75</sup>, it is known that:

- Nursing time cost accounts for 90% of the overall cost of pressure ulcer treatment
- Cost of prevention is almost four times higher in hospitalised patients compared to patients in home care or nursing homes
- The average cost of treatment per patient increases with severity of pressure ulcer
- Prevention is cost-saving compared to standard care and could potentially reduce incidence and prevalence of hospital-acquired pressure ulcers.

Furthermore, pressure ulcer prevention when linked to education and the use of a skin care regimen has been shown to reduce the incidence of pressure ulcers in hospitalised patients with incontinence and was associated with a 5% reduction in pressure ulcer management costs<sup>76</sup>.



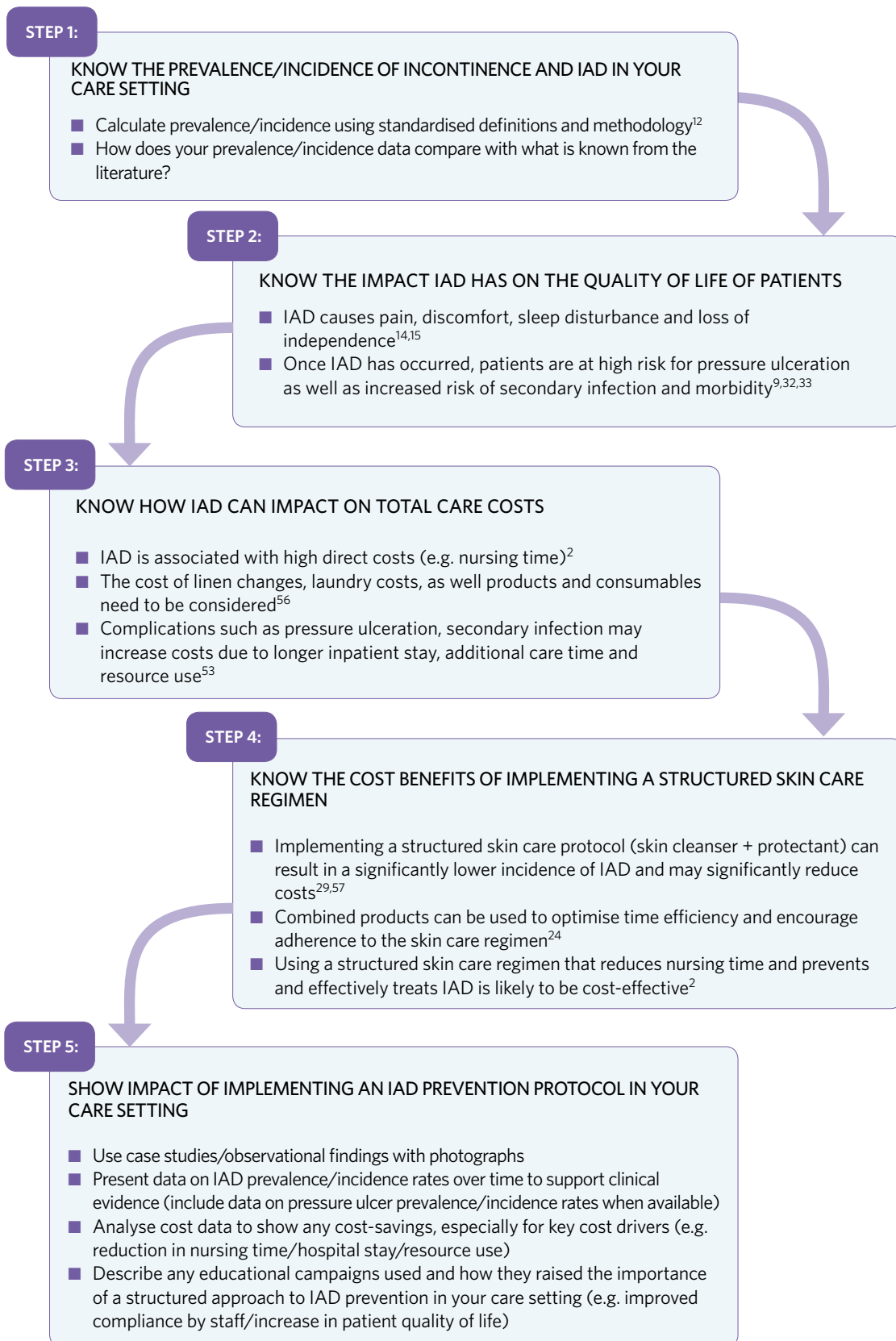
**All patients with incontinence are at risk of IAD. An individualised prevention plan should be implemented to reduce risk of both IAD and pressure ulceration**

Based on this, the expert panel suggest five steps, which can be used to make a case for funding of a structured skin care regimen for incontinent patients as part of a pressure ulcer prevention care plan (Figure 9).



**The measures outlined in this document for the prevention and management of IAD can be used as part of a pressure ulcer prevention programme and are in line with the recommendations of the National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance Clinical Practice Guidelines<sup>30</sup>**

**Figure 9** | Five steps to making the case for a standardised IAD prevention protocol



## APPENDIX A | Glossary of terms

<b>3-in-1</b>	Used to describe skin care products that combine cleansing with a skin protectant and moisturising function
<b>cleanser</b>	A product used to clean skin; contains surfactants and may be combined with other ingredients
<b>cosmetic</b>	A substance or mixtures of substances intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, etc.) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours
<b>dimethicone</b>	A silicone-based substance that forms a protectant barrier when applied to skin; one of a group of oils known as siloxanes
<b>emollient</b>	A substance that softens and smoothes the skin, usually via occlusion and by filling in the crevices between corneocytes
<b>humectant</b>	A molecule used in skin care products that attracts and retains water to promote hydration
<b>incidence</b>	Indicates the proportion of the population studied that develops a given medical condition over a specified time period
<b>lipophilic</b>	Fat-loving chemicals that are more or less insoluble in water. They are generally used to support the lipid layer of the skin
<b>moisturiser</b>	Leave-on skin care products that soften, smooth and hydrate the skin
<b>no-rinse</b>	A cleansing product that does not need to be rinsed off skin after use; usually has the advantage of being quick drying. Avoids friction that happens when drying the skin with a towel
<b>prevalence</b>	Refers to the total number of individuals in a population who have a medical condition at a specific point in time
<b>siloxane</b>	Another term for silicone-based products such as dimethicone used as barriers in skin care
<b>surfactant</b>	A molecule that reduces surface tension and aids cleansing
<b>TEWL</b>	The rate at which water is lost through skin; used as a measure of skin barrier function, e.g. high TEWL is indicative of impaired barrier function

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